K031505
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510(K) Summary

1. **Device Trade Name**
   RAPIDO™ Cut-Away™ Guiding Catheter

2. **Device Common Name**
   Percutaneous Catheter

3. **Device Description**

   The RAPIDO Cut-Away Guiding Catheter is similar to the approved RAPIDO Guiding Catheter. The Cut-Away Catheter is comprised of a flexible shaft, luer (hub) and a soft tip. The catheter shaft is comprised of an inner liner of polytetrafluoroethylene (PTFE), an outer layer of radiopaque polyether block amide (PEBAX), with a reinforcing layer of 304V stainless steel braid sandwiched between the two. A blue PEBAX luer (sometimes referred to as a "hub") is attached to the proximal end of the shaft using a cyanoacrylate adhesive. A silicone coating is applied to the exterior of the shaft to improve device lubricity. The distal end of the catheter is formed into a variety of shapes as needed to access differing areas of the anatomy.

4. **Intended Use**
   The Guidant RAPIDO™ Guiding Catheter is intended to access the coronary venous system, and may be used as a dual-catheter assembly. The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

5. **Technological Characteristics**
   Comparisons of the RAPIDO Cut-Away Guiding Catheters and predicate devices show that the technological characteristics such as design and intended use are substantially equivalent to the currently marketed predicate device.

6. **Performance Data**
   Testing demonstrated that the RAPIDO Cut-Away Guiding Catheters met the acceptance criteria and performed similarly to the predicate device . No new safety or effectiveness issues were raised during the testing program. The RAPIDO Cut-Away Guiding Catheter may be considered substantially equivalent to the predicate device.

7. **Conclusion**
   The Guidant RAPIDO Cut-Away Guiding Catheters are substantially equivalent to the currently marketed Guidant RAPIDO Guiding Catheter (K021455, cleared August 02, 2002) with regards to intended use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2003

Guidant Coporation
Cardiac Rhythm Management
c/o Mr. Shah M. Hilali
Senior Regulatory Affairs Associate
4100 Hamline Avenue North
St. Paul, MN 55112

Re: K031505
Trade Name:RAPIDO™ Cut-Away™ Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: May 14, 2003
Received: May 14, 2003

Dear Mr. Hilali:

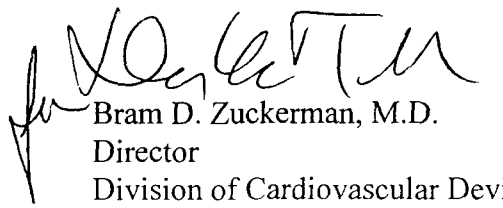
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031505

Special 510(k) **K031505**

Manufacturer: GUIDANT Corporation

Device Name: RAPIDO™ Cut-Away™ Guiding Catheter

Indications for Use: The Guidant RAPIDO™ Cut- Away™ Guiding Catheter is intended to access the coronary venous system, and may be used as a dual-catheter assembly. The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031505

Prescription Use Only